



UNITED STATES PATENT AND TRADEMARK OFFICE

u
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,519	03/03/2006	Hilary Clark	P1984R1	2294

9157 7590 10/22/2007
GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
----------	--------------

1647

MAIL DATE	DELIVERY MODE
-----------	---------------

10/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/533,519

Applicant(s)

CLARK ET AL.

Examiner

Marianne P. Allen

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

A substitute specification is required pursuant to 37 CFR 1.125(a) because the font size of the specification is too small and cannot be easily read. See MPEP 608.01 concerning appropriate font sizes and styles.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Art Unit: 1647

Group I, claim(s) 1-6, drawn to nucleic acids encoding polypeptides.

Group II, claim(s) 7-9 and 12-15 (in part), drawn to polypeptides.

Group III, claim(s) 10-11 and 12-15 (in part), drawn to antibodies.

Group IV, claim(s) 12-15 (in part), drawn to agonists.

Group V, claim(s) 12-15 (in part), drawn to antagonists.

Group VI, claim(s) 16-17 (in part), drawn to a method of treating an immune disorder with a polypeptide.

Group VII, claim(s) 16-17 (in part), drawn to a method of treating an immune disorder with an agonist.

Group VIII, claim(s) 16-17 (in part), drawn to a method of treating an immune disorder with an antagonist.

Group IX, claim(s) 16-17 (in part), drawn to a method of treating an immune disorder with an antibody.

Group X, claim(s) 18, drawn to a method for determining the presence of a polypeptide.

Group XI, claim(s) 19, drawn to a method of diagnosing an immune related disease by detecting a level of expression.

Group XII, claim(s) 20, drawn to a method of diagnosing an immune related disease using an antibody.

Group XIII, claim(s) 21, drawn to a method of identifying a compound that inhibits by determining lack of responsiveness.

Group XIV, claim(s) 22-23, drawn to a method of identifying a compound that inhibits by determining lack of expression of a gene.

Group XV, claim(s) 24, drawn to a method of identifying a compound that mimics activity.

Group XVI, claim(s) 25, drawn to a method of stimulating the immune response in a mammal.

Group XVII, claim(s) 26, drawn to a method of diagnosing an inflammatory immune response in a mammal.

Group XVIII, claim(s) 27, drawn to a method of differentiating monocytes.

Claims 12-15 are directed to multiple distinct products and will only be examined with respect to the invention elected.

Claims 16-17 are directed to multiple distinct methods and will only be examined with respect to the invention elected.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct SEQ ID Numbers. Each sequence is patentably distinct because they are structurally unrelated sequences, and a further restriction is applied to each Group. Applicant must further elect a single SEQ ID Number that lists or encodes an amino acid sequence or that lists a nucleotide sequence (See MPEP 803.04).

Applicant is advised that examination will be restricted to only the elected SEQ ID NO. and should not to be construed as a species election.

The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is directed to a single general inventive concept including a first appearing product and first appearing method of using the product. PCT Rule 13 does not provide for multiple products and methods. The remaining groups are directed to products with different structures and functions as well as methods that do not use the product of Group I. These additional methods use different starting materials, have different method steps, and/or have different goals. Each of SEQ ID NOS: 1-2517 is directed to

Art Unit: 1647

a structurally distinct product. There is no evidence of record of any common structural feature for these sequences.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of

Art Unit: 1647

the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Effective November 1, 2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter “5/25 claim threshold”). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and

Art Unit: 1647

Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21, 2007), 1322 Off. Gaz. Pat. Office 76 (Sept. 11, 2007) (final rule). The changes to 37 CFR 1.75(b) apply to any pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1, 2007. Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html>.

In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the restriction requirement as a reply. A SRR alone will not be considered a *bona-fide* reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims, applicant may file an amendment canceling a number of elected claims so that the elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed on or after November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within **TWO MONTHS** from

Art Unit: 1647

the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

If the restriction requirement is mailed before November 1, 2007, the election must be filed within **ONE MONTH** or THIRTY DAYS, whichever is longer, from the mailing date of this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25 total claims taking into account any amendment to the claims, the Office will notify applicant and provide a time period in which applicant is required to file an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Marianne P. Allen
Primary Examiner
Art Unit 1647

10/17/07

mpa